

ASSEMBLY BILL

No. 1437

Introduced by Assembly Member Koretz

February 21, 2003

An act to add Article 6 (commencing with Section 110424.8) to Chapter 4 of Part 5 of Division 104 of the Health and Safety Code, and to add Section 14105.37 to the Welfare and Institutions Code, relating to drug marketing practices.

LEGISLATIVE COUNSEL'S DIGEST

AB 1437, as introduced, Koretz. Drug marketing practices.

Existing law, the Sherman Food, Drug, and Cosmetic Law, contains various provisions regarding the packaging, labeling, and advertising of food, drugs, and cosmetics. A violation of any of these provisions is punishable as a misdemeanor.

This bill would make it unlawful, under that law, for any person to engage in inappropriate marketing of any drug or device used in the treatment of life-threatening chronic conditions to physicians or other medical providers.

This bill would also require every pharmaceutical manufacturing company to disclose to the State Department of Health Services the value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit provided in connection with certain drug marketing activities, with certain exceptions.

This bill would create a new crime, thereby imposing a state-mandated local program.

Existing law provides for the Medi-Cal program, administered by the State Department of Health Services, under which qualified low-income persons are provided with health care services, including

prescription benefits. Under existing law, the department pays participating pharmacists a discounted price for drugs on a Medi-Cal list of contract drugs, and obtains best price rebates from drug manufacturers.

This bill would require the department, during each negotiation with a manufacturer regarding the purchase price of a drug or drugs used to treat a life-threatening condition, to require the manufacturer to disclose the aggregate marketing costs for the drug or drugs that are the subject to the negotiation.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Article 6 (commencing with Section 110424.8)
2 is added to Chapter 4 of Part 5 of Division 104 of the Health and
3 Safety Code, to read:

4
5 Article 6. Drug Marketing Practices
6

7 110424.8. (a) It is unlawful for any person to engage in
8 inappropriate marketing of any drug or device used in the
9 treatment of life-threatening chronic conditions to physicians or
10 other medical providers.

11 (b) For purposes of this section, “inappropriate marketing”
12 means any action intended to entice a physician or other medical
13 provider to employ a drug or device in the treatment of a patient
14 by offering any of the following:

15 (1) Cash payments to physicians of any kind.

16 (2) Gifts to physicians that are not directly related to the benefit
17 of the patient or the practice of the physician related to the drug or
18 device.

19 (3) Travel, meals, or lodging for the physician unless they are
20 associated with legitimate physician education.

1 (4) Any payment or subsidy for other cost that is not directly
2 related to the benefit of the patient or the practice of the physician
3 related to the drug or device.

4 (c) For purposes of this section, “life-threatening chronic
5 condition” means a condition or disease that requires specialized
6 medical care over a prolonged period of time and will result in
7 death within five years without an appropriate drug regimen.

8 110424.85. (a) Every pharmaceutical manufacturing
9 company shall disclose to the department, on a quarterly basis, the
10 value, nature, and purpose of any gift, fee, payment, subsidy or
11 other economic benefit provided in connection with detailing,
12 promotional, or other marketing activities by the company,
13 directly or through its pharmaceutical marketers, to any physician,
14 hospital, nursing facility, pharmacist, health benefit plan
15 administrator or any other person in California authorized to
16 prescribe, dispense, or purchase prescription drugs in this state.
17 Disclosure shall be made on a form and in a manner prescribed by
18 the department.

19 (b) Each company subject to the requirements of subdivision
20 (a) shall also disclose to the department annually the name and
21 address of the individual responsible for compliance with that
22 subdivision.

23 (c) The department shall keep confidential all trade secret
24 information disclosed to the department pursuant to subdivision
25 (a). The disclosure form prescribed by the department shall permit
26 the company to identify any information that is a trade secret.

27 (d) The following shall be exempt from disclosure:

28 (1) Free samples of prescription drugs intended to be
29 distributed to patients.

30 (2) The payment of reasonable compensation and
31 reimbursement of expenses in connection with bona fide clinical
32 trials. As used in this paragraph, “clinical trial” means an
33 approved clinical trial conducted in connection with a research
34 study designed to answer specific questions about vaccines, new
35 therapies, or new ways of using known treatments.

36 (3) Any gift, fee, payment, subsidy, or other economic benefit
37 the value of which is less than twenty-five dollars (\$25).

38 (4) Scholarship or other support for medical students,
39 residents, and fellows to attend a significant educational,
40 scientific, or policymaking conference of a national, regional, or

1 specialty medical or other professional association if the recipient
2 of the scholarship or other support is selected by the association.

3 (e) As used in this section:

4 (1) “Pharmaceutical marketer” means a person who, while
5 employed by or under contract to represent a pharmaceutical
6 manufacturing company, engages in pharmaceutical detailing,
7 promotional activities, or other marketing of prescription drugs in
8 the state to any physician, hospital, nursing home, pharmacist,
9 health benefit plan administrator, or any other person authorized
10 to prescribe, dispense, or purchase prescription drugs. The term
11 does not include a wholesale drug distributor or the distributor’s
12 representative who promotes or otherwise markets the services of
13 the wholesale drug distributor in connection with a prescription
14 drug.

15 (2) “Pharmaceutical manufacturing company” means any
16 entity which is engaged in the production, preparation,
17 propagation, compounding, conversion, or processing of
18 prescription drugs, either directly or indirectly by extraction from
19 substances of natural origin, or independently by means of
20 chemical synthesis, or by a combination of extraction and
21 chemical synthesis, or any entity engaged in the packaging,
22 repackaging, labeling, relabeling, or distribution of prescription
23 drugs. The term does not include a wholesale drug distributor or
24 pharmacist.

25 SEC. 2. Section 14105.37 is added to the Welfare and
26 Institutions Code, to read:

27 14105.37. During each negotiation with a manufacturer
28 regarding the purchase of a drug or drugs that are used to treat a
29 life-threatening condition, the department shall require the
30 manufacturer to disclose the aggregate marketing costs for the
31 drug or drugs that are the subject of that negotiation. The
32 department shall keep this data confidential, although the
33 department, on an annual basis and without identifying any
34 manufacturer in any way, shall provide aggregate marketing cost
35 information to the relevant committees in both houses of the
36 Legislature and to the Legislative Analyst.

37 SEC. 3. No reimbursement is required by this act pursuant to
38 Section 6 of Article XIII B of the California Constitution because
39 the only costs that may be incurred by a local agency or school
40 district will be incurred because this act creates a new crime or

1 infraction, eliminates a crime or infraction, or changes the penalty
2 for a crime or infraction, within the meaning of Section 17556 of
3 the Government Code, or changes the definition of a crime within
4 the meaning of Section 6 of Article XIII B of the California
5 Constitution.

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